

## Department of Health and Human Services

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applies them to disclosure determinations. (In some cases more than one exemption may apply to the same document.) Information obtained by the Department from any individual or organization, furnished in reliance on a provision for confidentiality authorized by applicable statute or regulation, will not be disclosed, to the extent it can be withheld under one of these exemptions. This section does not itself authorize the giving of any pledge of confidentiality by any officer or employee of the Department.

### **§ 5.62 Exemption one: National defense and foreign policy.**

We are not required to release records that, as provided by FOIA, are “(a) specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and (b) are in fact properly classified pursuant to such Executive Order.” Executive Order No. 12356 (1982) provides for such classification. When the release of certain records may adversely affect U.S. relations with foreign countries, we usually consult with officials of those countries or officials of the Department of State. Also, we may on occasion have in our possession records classified by some other agency. We may refer your request for such records to the agency that classified them and notify you that we have done so, as explained in § 5.23.

### **§ 5.63 Exemption two: Internal personnel rules and practices.**

We are not required to release records that are “related solely to the internal personnel rules and practices of an agency.” Under this exemption, we may withhold routine internal agency practices and procedures. For example, we may withhold guard schedules and rules governing parking facilities or lunch periods. Also under this exemption, we may withhold internal records whose release would help some persons circumvent the law or agency regulations. For example, we ordinarily do not disclose manuals that instruct our investigators or auditors how to investigate possible violations of law, to the extent that this release

would help some persons circumvent the law.

### **§ 5.64 Exemption three: Records exempted by other statutes.**

We are not required to release records if another statute specifically allows us to withhold them. We may use another statute to justify withholding only if it absolutely prohibits disclosure or if it sets forth criteria to guide our decision on releasing or identifies particular types of material to be withheld.

### **§ 5.65 Exemption four: Trade secrets and confidential commercial or financial information.**

We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

(a) *Trade secrets.* A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) *Commercial or financial information.* We will not disclose records whose information is “commercial or financial,” is obtained from a person, and is “privileged or confidential.”

(1) Information is “commercial or financial” if it relates to businesses, commerce, trade, employment, profits, or finances (including personal finances). We interpret this category broadly.

(2) Information is “obtained from a person” if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. “Person” includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not “obtained from a person” if it is generated by HHS or another federal agency. However, information is “obtained from a person” if it is provided by someone, including but not limited to an agency employee, who retains a

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commercial or financial interest in the information.

(3) Information is “privileged” if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.

(4) Information is “confidential” if it meets one of the following tests:

(i) Disclosure may impair the government’s ability to obtain necessary information in the future;

(ii) Disclosure would substantially harm the competitive position of the person who submitted the information;

(iii) Disclosure would impair other government interests, such as program effectiveness and compliance; or

(iv) Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one or more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

(c) *Designation of certain confidential information.* A person who submits records to the government may designate part or all of the information in such records as exempt from disclosure under Exemption 4 of the FOIA. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215–12, then that legend is necessary for this purpose. Any

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such designation will expire ten years after the records were submitted to the government.

(d) *Predisclosure notification.* The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (c) of this section. They also apply to records that were submitted to the government where we have substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. Certain exceptions to these procedures are stated in paragraph (e) of this section.

(1) When we receive a request for such records, and we determine that we may be required to disclose them, we will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If we must notify a large number of submitters, we may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has five working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.

(3) We will give consideration to all bases that have been timely stated by the submitter. If we decide to disclose the records, we will notify the submitter in writing. This notice will briefly explain why we did not sustain its objections. We will include with the notice a copy of the records about which the submitter objected, as we propose to disclose them. The notice will state that we intend to disclose the records five working days after the submitter receives the notice unless we are ordered by a United States District Court not to release them.

(4) When a requester files suit under the FOIA to obtain records covered by this paragraph, we will promptly notify the submitter.

(5) Whenever we send a notice to a submitter under paragraph (d)(1) of

this section, we will notify the requester that we are giving the submitter a notice and an opportunity to object. Whenever we send a notice to a submitter under paragraph (d)(3) of this section, we will notify the requester of this fact.

(e) *Exceptions to predisclosure notification.* The notice requirements in paragraph (d) of this section do not apply in the following situations:

(1) We decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation, issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the FOIA, but in this case a submitter may still designate records as described in paragraph (c) of this section, and in exceptional cases, we may, at our discretion, follow the notice procedures in paragraph (d) of this section; or

(4) The designation appears to be obviously frivolous, but in this case we will still give the submitter the written notice required by paragraph (d)(3) of this section (although this notice need not explain our decision or include a copy of the records), and we will notify the requester as described in paragraph (d)(5) of this section.

#### **§ 5.66 Exemption five: Internal memoranda.**

This exemption covers internal government communications and notes that fall within a generally recognized evidentiary privilege. Internal government communications include an agency's communications with an outside consultant or other outside person, with a court, or with Congress, when those communications are for a purpose similar to the purpose of privileged intra-agency communications. Some of the most-commonly applicable privileges are described in the following paragraphs.

(a) *Deliberative process privilege.* This privilege protects predecisional deliberative communications. A communication is protected under this privilege if it was made before a final decision was reached on some question of

policy and if it expressed recommendations or opinions on that question. The purpose of the privilege is to prevent injury to the quality of the agency decisionmaking process by encouraging open and frank internal policy discussions, by avoiding premature disclosure of policies not yet adopted, and by avoiding the public confusion that might result from disclosing reasons that were not in fact the ultimate grounds for an agency's decision. Purely factual material in a deliberative document is within this privilege only if it is inextricably intertwined with the deliberative portions so that it cannot reasonably be segregated, if it would reveal the nature of the deliberative portions, or if its disclosure would in some other way make possible an intrusion into the decisionmaking process. We will release purely factual material in a deliberative document unless that material is otherwise exempt. The privilege continues to protect predecisional documents even after a decision is made.

(b) *Attorney work product privilege.* This privilege protects documents prepared by or for an agency, or by or for its representative (typically, HHS attorneys) in anticipation of litigation or for trial. It includes documents prepared for purposes of administrative adjudications as well as court litigation. It includes documents prepared by program offices as well as by attorneys. It includes factual material in such documents as well as material revealing opinions and tactics. Finally, the privilege continues to protect the documents even after the litigation is closed.

(c) *Attorney-client communication privilege.* This privilege protects confidential communications between a lawyer and an employee or agent of the government where there is an attorney-client relationship between them (typically, where the lawyer is acting as attorney for the agency and the employee is communicating on behalf of the agency) and where the employee has communicated information to the attorney in confidence in order to obtain legal advice or assistance.